Title II of the Drug Quality and Security Act of 2013

The Drug Quality and Security Act (DQSA), was signed into law by President Obama on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

Ten years after enactment, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain. The new system will:

- enable verification of the legitimacy of the drug product identifier down to the package level;
- enhance detection and notification of illegitimate products in the drug supply chain; and
- facilitate more efficient recalls of drug products.

Drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) will be called on to work in cooperation with FDA to develop the new system over the next 10 years.

Among key provisions implemented over the next 10 years are requirements for:

- **Product identification**: Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.
- **Product tracing**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.
- **Product verification**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.
- **Detection and response**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as *suspect*, meaning that it may be counterfeit, unapproved, or potentially dangerous.
- **Notification**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.
- **Wholesaler licensing**: Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.
- **Third-party logistics provider licensing**: Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.

The law requires FDA to develop standards, guidance documents, and pilot programs and to conduct public meetings, in addition to other efforts necessary to support efficient and effective implementation. FDA is developing a schedule for implementing the law's requirements.

This system will enhance the U.S. Food and Drug Administration's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers. Failure to comply with the requirements of the law can result in penalties.

The development of the system will be phased in with new requirements over a 10-year period. These requirements will include providing product and transaction information at each sale with lot level information, in paper or electronic format, and placing unique product identifiers on individual drug packages.

Taken from the website from the U.S. Food and Drug Administration:

https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/